Critical Drug Shortage
Heparin

MASSACHUSETTS GENERAL HOSPITAL

Heparin Shortage: Your Questions Answered

Why is there a heparin shortage? Heparin is an anticoagulant that is derived from pigs. An outbreak of African swine fever in China has drastically reduced its pig population by an estimated 40 percent. Because 80 percent of crude heparin available globally is produced in China (with 60 percent supplied to the U.S.), we are at a critical point where all manufacturers are experiencing delays in supplying heparin products.

What does our current inventory look like? It is important to remember that inventory fluctuates daily. The heparin shortage Apollo page is updated regularly to reflect the current inventory at MGH. For the most up-to-date information for supplies in your area, please reach out to your service lead representatives.

Some of my colleagues at other hospitals say they haven't heard about a heparin shortage. Or, they believe their institutions do not have a heparin shortage. Why is this? The MGH Department of Pharmacy has been in direct communication with leaders at other hospitals and departments across the United States who assure us that they are experiencing similar shortage concerns. While some hospitals may be responding in a less visible fashion, the MGH and BWH – based on our large size and high utilization of heparin – have taken the approach of considering this a hospital emergency. In response, both institutions have activated the Hospital Incident Command System (HICS), allowing for improved management, communication and collaboration systemwide.

What is happening at the Partners level to address the heparin shortage? Partners HealthCare is actively monitoring the shortage through a multidisciplinary team, including Emergency Preparedness, Chief Pharmacy Officers Council, Supply Chain, Quality, Safety and Value. Partners institutions continue to work collaboratively and to share active conservation efforts and areas of concern. Each institution is closely monitoring its inventory.

What are our purchase strategies? Why can't we simply purchase from another manufacturer or make our own supply? We have a pharmacist dedicated to reviewing our daily inventory and our supply of backordered items. We maintain a contract with a primary wholesaler, secondary wholesaler, and we purchase directly from manufacturers. Not all manufacturers, however, make all formulations of heparin that we use. Additionally, when contracts are written, manufacturers are required to supply their committed customers prior to supplying those who signed a contract with a competitor. For example, if we sign a contract with a company to purchase 2 unit/mL 500 mL heparin but the company is unable to supply us with the drug, we could not order from another manufacturer until it first fulfilled all the orders of the institutions they have contracts with.

If I visit the FDA website, it does not mention the shortage. Why is this? The Food and Drug Administration (FDA) often waits to list medications until all options of a particular drug are marked as "unavailable." Currently with the heparin shortage, at least one manufacturer lists the product as available despite our inability to readily procure it. The American Society of Health Pharmacists lists all strengths of heparin vials as well as premix bags on shortage.

Why can't companies make more heparin to meet increased demand? Unfortunately, this is a complex and involved process that involves FDA approval. If a company is not previously FDA-approved to produce heparin, the manufacturer would need to apply for approval and then go through a formal inspection. In addition, the companies that produce the raw heparin materials (active pharmaceutical ingredient producers) must also receive FDA approval before entering the market. These processes often take several months or more to complete.

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I keep hearing the world "allocation?" What does it mean? During a drug shortage, manufacturers and wholesalers may look at historic utilization to determine how much of the drug we will be able to receive. The allocation process is used to prevent one institution from over-purchasing, leaving other institutions struggling with little to no product. Allocations are, however, only useful so long as there is product to supply. Allocations are not a guarantee of product on a regular basis.

Why can't the pharmacy just make smaller vial sizes of heparin from the larger vials available to increase our supply of heparin? This is a logical question and something that we continue to monitor for feasibility. Unfortunately, due to increased regulatory oversight of compounding practices, there are strict rules imposed upon repackaged sterile products that severely limit the shelf life of any product that is compounded by the pharmacy. With each manipulation of a sterile product, there is increased risk of contamination and consequently a much shorter duration until the product must be used. For example, we may repackage a commercially available heparin vial with a two-year shelf life into smaller vials that must be used in less than two days – or within a week if the supply remains in a refrigerated storage location until it is used. This strategy presents considerable logistical challenges and requires a delicate balance of maintaining an appropriate supply of compounded product while minimizing waste due to quickly expiring product. We continue to assess this approach as an option of last resort. While we maintain a supply of most commercial products in container sizes routinely used at MGH, we believe it is our best option to continue using the commercial supply. However, if certain commercial offerings become exhausted, we will reassess our options of using less favorable, larger package sizes to compound preferable smaller sizes of heparin supplies.

We've been talking about this shortage for more than a month. Why haven't we run out of heparin? The MGH has taken a proactive effort to addressing this shortage, including activation of our Hospital Incident Command System. Hospital wide, all units have been implementing conservation and waste-reducing strategies, which have shown improvements to our heparin inventory. Educational tools continue to be developed to ensure any changes are done safely.

This shortage seems to be the latest in a list of recent shortages. Why do I hear about drug shortages so much more than I used to? Drug shortage experts at the FDA and the University of Utah Drug Information Service who monitor these incidents confirm that new drug shortages are increasing in both frequency and duration. One reason behind some shortages is that historical demand has outpaced manufacturer supplies. Our ability to mitigate and weather a drug shortage often depends on an item's return to market within a relatively short period. In some cases, manufacturers can shift forecasts and production schedules, however, this requires the company to seek FDA approval when they need to make changes to production lines – so this often is a last resort.

If my colleagues have questions about the shortage, who do I direct them to and where do I find the most up-to-date information? As part of the heparin shortage response, service leads have been identified for departments across the MGH. Service leads are made up of physician, nursing, and administration representation. To determine who your service lead is and to learn the latest about the shortage, please check out the Heparin Shortage Apollo page. As a reminder, service leads are the best resource for any departmental changes.

Who can I contact if I have clinical questions about whether my patient needs heparin or about use of alternative therapies? Hematology and Pharmacy have set up 24/7 pagers to help assist with clinical questions around use of heparin and/or alternative therapies. To see who is on-call this week, visit the Questions for Pharmacy/Hematology section on Apollo.

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